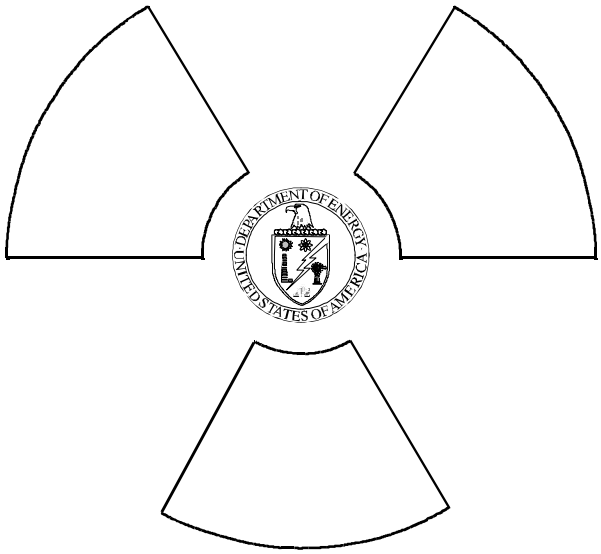
Print

DOE G 441.1-3
(formerly G-10 CFR 835/C1)
03-17-99

INTERNAL DOSIMETRY PROGRAM GUIDE

for use with

Title 10, Code of Federal Regulations, Part 835, Occupational Radiation Protection



Assistant Secretary for Environment, Safety and Health

(THIS PAGE INTENTIONALLY LEFT BLANK)

CONTENTS

ACRONYMS

AEC	Atomic Energy Commission
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANSI	American National Standards Institute
BZ	breathing zone
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
DAC	derived air concentration
DL	decision level
DIL	derived investigation level
DOE	U.S. Department of Energy
DOELAP	DOE Laboratory Accreditation Program
EPA	Environmental Protection Agency
FR	Federal Register
ICRP	International Commission on Radiological Protection
IL	investigation level
MDA	minimum detectable amount/activity
NCRP	National Council on Radiation Protection and Measurements
TEDE	total effective dose equivalent

INTERNAL DOSIMETRY PROGRAM

1. PURPOSE AND APPLICABILITY

This Guide provides an acceptable methodology for establishing and operating an internal dosimetry program that will comply with U.S. Department of Energy (DOE) requirements specified in Title 10 of the Code of Federal Regulations (CFR), Part 835, Occupational Radiation Protection (DOE 1998a); hereinafter referred to as 10 CFR 835. In particular, this Guide provides guidance for achieving compliance with subpart E, paragraphs 402(c) and 402(d) of 10 CFR 835 for the establishment, operation, and accreditation of bioassay programs. For completeness, this Guide also identifies applicable recommendations provided in DOE-STD-1121-98, INTERNAL DOSIMETRY (DOE 1998b), and recommendations contained in secondary documents (American National Standards Institute (ANSI) Standards, etc.).

This Guide amplifies the regulatory requirements of 10 CFR 835 and provides guidance for the structure, function, and operations of an internal dosimetry program. The criteria for internal dosimetry programs to serve epidemiology, risk assessment, and litigation are not within the scope of this Guide. The requirements of 10 CFR 835 are enforceable under the provisions of Sections 223(c) and 234A of the Atomic Energy Act of 1954, as amended (AEC 1954).

Except for requirements established by a regulation, a contract, or by administrative means, the provisions in this Guide are DOE's views on acceptable methods of program implementation and are not mandatory. Conformance with this Guide will, however, create an inference of compliance with the related regulatory requirements. Alternate methods that are demonstrated to provide an equivalent or better level of protection are acceptable. Contractors are encouraged to go beyond the minimum requirements and to pursue excellence in their programs.

The word "shall" is used in this Guide to designate requirements from 10 CFR 835. Compliance with 10 CFR 835 is mandatory except to the extent an exemption has been granted pursuant to 10 CFR 820, Procedural Rules for DOE Nuclear Activities (DOE 1997a). The words "should" and "may" are used to represent optional program recommendations and allowable alternatives, respectively.

This Guide is applicable to all DOE activities that are subject to the requirements of 10 CFR 835.

2. DEFINITIONS

Terms defined in 10 CFR 835 are used in this Guide consistent with their regulatory definitions.

Alpha (α): The probability (not to be confused with an alpha particle) of a *Type I error* or *false positive*. Also called the false positive probability.

Analyte: The particular radionuclide to be determined in a sample of interest.

Baseline bioassay: An appropriate bioassay measurement obtained from a radiobioassay program participant prior to beginning or resuming work with radioactive material.

Beta (β): The probability (not to be confused with a beta particle) of a *Type II error* or *false negative*. Also called the non-detection probability.

Confirmed intake: An intake confirmed by follow-up radiobioassay, by association with a known incident, or by investigation.

Decision level (L_c): The amount of a count (L_c or L'_c) as final instrument measurement of a quantity of analyte (D_c or D'_c) at or above which a decision is made that the analyte is definitely present.

Derived investigation level (*DIL*): A value of a radiobioassay or air monitoring measurement that indicates an intake resulting in a dose exceeding an Investigation Level *(IL).*

Direct (in vivo) radiobioassay: The measurement of radioactive material in the human body utilizing instrumentation that detects radiation emitted from the radioactive material in the body.

DOELAP: The Department of Energy Laboratory Accreditation Program. This program defines a set of reference performance tests and provides a description of the minimum levels of acceptable performance for personnel dosimetry systems and radiobioassay programs under DOE STD-1112-98, THE DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM FOR RADIOBIOASSAY (DOE 1998c).

Elimination: The biological removal of a radionuclide from the body by excretion, perspiration, exhalation, secretion (e.g., breast milk), exfoliation (sloughing of dead tissue), or excision.

Evaluation: The process of arriving at a value for intake or dose that uses, among other inputs, measurement results.

Excretion: The biological removal of a radionuclide from the body via one or more excretion pathways: urine and feces.

Exposure: The general condition of being subjected to ionizing radiation, such as by exposure to ionizing radiation from external sources or to ionizing radiation sources inside the body. In this document, exposure does not refer to the radiological physics concept of charge liberated per unit mass of air.

False negative: A *Type II (β) error,* that is, concluding that *analyte* is not present when in fact it is.

False positive: A *Type I (α) error*, that is, concluding that there is *analyte* present when it is not.

Indirect (in vitro) radiobioassay: The measurement or analysis of radionuclides in excreta or other biological samples removed from the body.

Intake: The amount of radionuclide taken into the body by inhalation, absorption through intact skin, injection, ingestion, or through wounds. Depending on the radionuclide involved, intakes may be reported in mass (e.g., µg, mg), activity (e.g., µCi, Bq), or potential alpha energy (e.g., MeV, J) units.

Investigation level (*IL*): The value of the committed effective dose equivalent from an intake(s) of a radioactive material by a worker at or above which, for regulatory purposes, is regarded as sufficiently important to justify further investigation

Minimum detectable amount (*MDA*): The smallest amount (activity or mass) of an analyte in a sample that will be detected with a probability, β, of non-detection (*Type II error*) while accepting a probability, α, of erroneously deciding that a positive (non-zero) quantity of analyte is present in an appropriate blank sample (*Type I error*). The *MDA* is computed using the same value of α as used for the L_c. The *MDA* depends on both α and β. Measurement results are compared to the L_c, not the *MDA*; the *MDA* is used to determine whether a program has adequate detection capability. The *MDA* will be greater than or equal to the L_c.

Radon: Unless otherwise specified, the isotope ^{222}Rn.

Retention: The amount of material which, after being taken into the body by inhalation, ingestion, entry through an open wound, or absorption through the skin, exists in the whole body, a compartment, an organ, or a tissue at a specified time.

Routine radiobioassay monitoring: Any radiobioassay measurement made on a predetermined, periodic schedule, to establish whether a worker has had any intake of radioactive material since previous radiobioassay measurements.

Special radiobioassay monitoring: Any radiobioassay measurement that is required for confirmation of a suspected intake of radionuclides, or is required for follow-up evaluation of confirmed intakes.

State-of-the-art: The most advanced technology that is commercially available and successfully field tested.

Technology shortfall: A technology shortfall for routine radiobioassay exists when the derived investigation level (*DIL*) for a well-designed and appropriate routine radiobioassay program, using current or state-of-the-art methods and equipment, is less than the minimum detectable amount/activity of the routine monitoring method (e.g., the *DIL* is less than the *MDA*).

Termination radiobioassay: A radiobioassay measurement performed for the purpose of documenting the retention of radioactive materials in the body due to occupational exposure either upon termination of employment or upon the cessation of potential exposure to a specific nuclide.

Thoron: Unless otherwise specified, the isotope ^{220}Rn.

Type I error: Incorrectly concluding from a result that there is analyte present; the probability (α) of a *Type I error* is usually taken as 0.05. The *decision level* is determined on the basis of an acceptable level of *Type I errors*.

Type II error: Incorrectly concluding from a result that there is no analyte present; its probability (β) is usually taken as 0.05.

3. DISCUSSION

Radiation protection programs for limiting intakes of radioactive material are based on the DOE policy of controlling radioactive material at the source. It is nonetheless recognized that low-level, chronic, or intermittent occupational exposures to some materials may be difficult to avoid due to the types of material handled or processed, their chemical or physical forms, and the nature of operations, and that incidents may cause unplanned releases of radioactive material. 10 CFR 835.402(c) requires internal dosimetry programs (including routine radiobioassay programs) be conducted for radiological workers, declared pregnant workers, occupationally exposed minors, and members of the public entering controlled areas who are likely to receive intakes that exceed specified levels for committed effective dose equivalent in a year. An internal dosimetry program generally consists of three elements:

- An air monitoring program, using a combination of real-time, fixed, and portable devices, as appropriate;
- an individual monitoring program, using direct and/or indirect radiobioassay, and personal breathing zone (BZ) air monitoring, as appropriate;
- a dose evaluation program that evaluates the data collected by the air and individual monitoring programs to determine the magnitude of individual doses.

4. IMPLEMENTATION GUIDANCE

This section provides guidance for establishing and conducting internal dosimetry programs for individuals who have the potential for intakes of radioactive materials. It includes guidance for design and implementation of the radiobioassay program, and guidance for evaluating, recording, reporting, and managing internal doses. Additional technical guidance is provided in DOE-STD-1121-98 and the National Council on Radiation Protection and Measurements (NCRP) Report No. 87, *Use of Radiobioassay Procedures for Assessment of Internal Radionuclide Deposition* (NCRP 1987).

An acceptable internal dosimetry program includes the following features:

- adequate staff with appropriate technical training;
- internal dosimetry technical basis documentation providing scientific information and other rationale explaining essential elements of the internal dosimetry program to support dose evaluation methods;
- written policies and procedures covering essential steps in the activities used to determine worker internal dose;
- criteria and methods for implementing an appropriate air monitoring program;
- defined criteria for identifying workers who need to participate in the individual monitoring program;
- appropriate radiobioassay measurement methods and frequencies;
- methods for control, accountability, and safe handling of samples;
- appropriate dosimetric models and default parameters for evaluating internal dose;
- timely analysis of radiobioassay samples and measurements, transmission of results, dose evaluation, and recommendations to operations management;
- adequate detection capability and quality of radiobioassay measurements;
- defined criteria and actions for identifying individuals with suspected intakes, based on workplace measurements and radiobioassay measurements;
- appropriate action level guidelines;
- defined program to report internal doses to workers, management, and DOE;
- historical records of radiobioassay measurement results and dose evaluations;
- historical records of the program, and changes in the program over time; and

- a quality assurance program covering essential steps in the activities that determine worker internal dose.

4.1 PROGRAM MANAGEMENT AND ADMINISTRATION

4.1.1 General Requirements

The internal dosimetry program shall be adequate to demonstrate compliance with the dose limits established in Subpart C of 10 CFR 835 (10 CFR 835.402(d)). In addition, radiobioassay programs implemented to demonstrate compliance with the requirements in 10 CFR 835.402(c) (individual monitoring thresholds) shall be:

- accredited or excepted from accreditation in accordance with the DOELAP for Radiobioassay (10 CFR 835.402(d)(1)); or

- determined by the Secretarial Officer responsible for environment, safety and health matters, currently the Assistant Secretary for Environment, Safety, and Health, to have performance substantially equivalent to that of programs accredited under DOELAP for radiobioassay (10 CFR 835.402(d)(2)).

Guidance for achieving accreditation or exception from accreditation under DOELAP is provided in DOE-STD-1111-98, DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM ADMINISTRATION (DOE 1998d). Requests for other program determinations will be considered by DOE on a case-by-case basis.

The provision requiring accreditation for radiobioassay programs implemented to demonstrate compliance with 10 CFR 835.402(c) does not reflect an intent to provide a lesser degree of protection to individuals unlikely to receive doses exceeding the regulatory monitoring thresholds, nor does it express a desire to establish two separate radiobioassay programs (i.e., an accredited program for individuals likely to exceed the regulatory monitoring thresholds and a non-accredited program for individuals who are unlikely to exceed these thresholds). Rather, those individuals who are unlikely to exceed the regulatory monitoring thresholds are provided an adequate degree of protection by the various engineering and administrative controls that limit their internal doses. Implementation of a comprehensive air monitoring program in accordance with 10 CFR 835.401 and 403 verifies the effectiveness of these controls. To the extent that management of any given facility chooses to provide individual monitoring to these individuals to validate the effectiveness of the design and administrative controls, air monitoring program, and contamination control program, individual monitoring may consist of radiobioassay under the accredited program, or other individual monitoring, such as individual personal BZ air monitoring, that falls outside the scope of the accredited program.

Sections 401 through 403 of 10 CFR 835 establish specific monitoring requirements for areas and individuals. 10 CFR 835 also establishes requirements for maintaining individual monitoring records (10 CFR 835.702) and reporting radiation doses to individuals (10 CFR 835.801).

4.1.2 Organization, Staffing, and Facilities

4.1.2.1 Organization

The internal dosimetry program should be administered by the radiological control organization under the leadership of the radiological control manager. The internal dosimetry program should have a designated leader with demonstrated expertise in internal dose evaluation.

When elements of the internal dosimetry program are performed by one or more subcontractors, the radiological control organization should establish an arrangement of contractual standards and assessments that ensure that subcontractors meet all applicable requirements in 10 CFR 835, the documented Radiation Protection Program (RPP), DOELAP standards, and the internal dosimetry technical basis document.

4.1.2.2 Staffing

The radiological control organization management should ensure that the internal dosimetry program is adequately staffed to carry out its functions. The analysis of workplace and radiobioassay measurement data and the evaluation of internal dose involve complex evaluation and professional judgment. Personnel with responsibility for internal dose evaluation should have the necessary expertise and skill, based on appropriate education and training in conjunction with practical experience, to perform their assigned duties. Additional guidance on education, skills, and training is provided in DOE G 441.1-1, MANAGEMENT AND ADMINISTRATION OF RADIATION PROTECTION PROGRAMS GUIDE (DOE 1999a). It is important that internal dosimetry specialists be capable of recognizing conditions warranting follow-up radiobioassay and dose evaluation. Personnel should be familiar with the relevant internal dosimetry literature and the recommendations of national and international scientific organizations with regard to internal dose evaluation.

Management of the radiological control organization should establish minimum requirements for those staff who evaluate internal doses. These requirements should include both experience and education requirements. Suggested educational background and formal training needed for internal dosimetry program key positions are listed in DOE-STD-1107-97, KNOWLEDGE, SKILLS, AND ABILITIES FOR KEY RADIATION PROTECTION POSITIONS AT DOE FACILITIES (DOE 1997b). Members of the internal dosimetry staff should meet these requirements, or the staff should have access to individuals with the required background (perhaps through interdepartmental agreements or contracted services). It is not necessary for all personnel on the staff to have expertise in all of the listed subject areas.

4.1.2.3 Facilities and Resources

Computational facilities and software tools used by internal dosimetry personnel should be adequate for performing calculations required for the evaluation of dose from radionuclides in the body. A library of handbooks, reference materials, scientific publications, and other resources pertaining to internal dosimetry should be readily available. Suggested reference materials are include the documents listed as references and other supporting documents provided in Sections 5 and 6 of this Guide.

4.1.3 Technical Basis Document

Internal dosimetry technical basis documentation should be developed and should include technical methods, supporting evidence, and reference information used to provide the technical foundation for the internal dosimetry program. The internal dosimetry technical basis documentation should provide the approach to evaluating internal doses from radiobioassay data, and for situations in which there is no practical radiobioassay, from representative air monitoring or other appropriate data. The technical basis documentation should address all of the topics listed under section 3.1, Internal Dosimetry Technical Basis Documentation of DOE-STD-1121-98. The technical basis documentation should be reviewed periodically and updated as necessary to ensure that the scientific bases are appropriate for current conditions. The technical basis documentation should be controlled and retained as a radiation protection program record.

4.1.4 Internal Dosimetry Procedures Manual

10 CFR 835 requires that written procedures be developed and implemented as necessary to ensure compliance, commensurate with the radiological hazards created by the activity and consistent with the education, training, and skills of the individuals exposed to those hazards (10 CFR 835.104). Essential elements of the internal dosimetry program should be addressed in written procedures. These procedures should be consistent with 10 CFR 835, the DOELAP standard, and technical basis documentation.

Detailed guidance on topics that should be addressed in the internal dosimetry procedures manual are discussed in Section 3.2, Internal Dosimetry Procedures Manual, of DOE-STD-1121-98. Additional guidance on written procedures is provided in DOE G 441.1-1.

4.1.5 Quality Assurance

Quality Assurance for internal dosimetry programs is addressed in DOE-STD-1121-98, Section 11, Quality Assurance. Quality assurance in support of internal dosimetry programs should be conducted in accordance with this DOE standard.

The internal dosimetry program should be included as a functional element subject to the internal audit requirements of 10 CFR 835.102. DOE G 441.1-1 provides guidance on internal audit programs. External peer-review by qualified individuals, on a periodic basis, is also recommended.

4.2 AIR MONITORING AND CONTAMINATION CONTROL PROGRAMS

The objectives of an air monitoring program are to verify the integrity of radioactive material containment, detect the release of radioactive materials from some routine operations, detect inadvertent releases of those materials in the workplace, evaluate and provide the basis for modification to containment systems, provide a basis for the design of radiobioassay programs, and verify that selected groups do not need to participate in a radiobioassay program. Air monitoring programs and internal dosimetry programs are complimentary. The air monitoring program provides an indication of the effectiveness of engineering and administrative controls in preventing or minimizing worker intakes and the internal dosimetry program provides verification of the adequacy of these controls in preventing or minimizing worker intakes.

The air monitoring and contamination control programs supplement the individual monitoring program by providing a prospective assessment of radiological conditions, facilitating decisions regarding postings, access controls, work authorizations, and individual monitoring, and providing back-up data for use in individual dose evaluations. Because of the need to evaluate individual internal doses from intakes of radioactive material from uncontained sources, airborne radioactive material, and surface contamination, the air monitoring and contamination control programs should include methods for assessing the degree of hazard arising from each of these hazards to which individuals may be exposed. Guidance for implementing contamination control and air monitoring programs is provided in DOE G 441.1-9, RADIOACTIVE CONTAMINATION CONTROL GUIDE (DOE 1999b), and DOE G 441.1-8, AIR MONITORING GUIDE (DOE 1999c) respectively.

In most cases the air monitoring program is used to supplement and validate the individual monitoring program. However, in the case when there is no practical radiobioassay method or when there is a technology shortfall (e.g., the *DIL* is less than the *MDA*) the air monitoring program may be the basis for the determination of internal doses. These two cases are discussed below.

4.2.1 Air Monitoring When There Is No Practical Radiobioassay Method

In situations where no radiobioassay method is available for the radionuclides in question, and no radiobioassay program, either routine or special, can show compliance with 10 CFR 835, personal (BZ) air monitoring may be used for demonstrating compliance with 10 CFR 835. BZ air monitoring is part of the Individual Monitoring Program which is detailed below. However, other fixed or portable monitoring instruments that provide either real-time (such as continuous air monitors) or retrospective (such as grab sampling which is analyzed at some time after the sample is collected) may be required when BZ monitoring data is not available or to supplement or validate the BZ data if it is available. Radionuclides with short half-lives, including the short-lived decay products of ^{222}Rn ("radon" decay products ^{218}Po, ^{214}Pb, ^{214}Bi, and ^{214}Po) and ^{220}Rn ("thoron" primary decay products ^{212}Pb and ^{212}Bi) are examples of radionuclides where intakes cannot be determined through radiobioassay and must be determined from personal air monitoring. For detailed information on non-background exposures to radon and thoron, see DOE-STD-1121-98, Section 4.5, Measurements of Workplace Radon and Thoron Concentrations, Potential Alpha Energy Concentrations, and Measurements of (or Assumptions About) Equilibrium Factors . Monitoring programs for Radon and Thoron should be in accordance with the DOE standard.

4.2.2 Recourse for Technology Shortfall (DIL<MDA)

DILs for reasonable and practical routine radiobioassay programs may be significantly less than the achievable *MDA* for certain radionuclides, such as plutonium. Since a technology shortfall for routine radiobioassay exists, the facility should consider the following actions (note that some of these suggested actions fall under the category of individual as opposed to area monitoring, but for completeness they are all listed below):

- enhance contamination and air monitoring and the use of indicators (e.g., unexpected glove or surface contamination, increase in airborne radioactive material contamination) to trigger early special radiobioassay monitoring;

- enhance personal contamination monitoring (e.g., clothing, skin, nasal smears) to trigger special radiobioassay monitoring;

- use the best practicable radiobioassay monitoring methods;

- implement enhanced design, operation, controls, and personnel protection equipment and procedures to minimize intakes;

- implement supplementary air monitoring; and

- document and justify the planned supplementary approach in the facility's internal dosimetry technical basis documentation.

When air monitoring data are used, each worker's stay times (in hours) and the average concentration (in DACs) to which the worker is exposed should be multiplied to yield exposures to airborne radioactive materials in units of DAC-hours. Forty (40) DAC-hours corresponds to 0.1 rem (0.001 Sv) committed effective dose equivalent for radionuclides with stochastic Annual Limits on Intake..

A technology shortfall for routine radiobioassay should not be sufficient cause for failing to place individuals on a minimum or best-available radiobioassay program.

Refer to DOE-STD-1121-98, Section 4.4.4, Supplementing Routine Radiobioassay Programs when *DIL<MDA*, for a discussion and examples of technology shortfalls and suggested methods to handle such situations.

4.3 INDIVIDUAL MONITORING PROGRAM

Individual monitoring programs should be designed in accordance with Section 4 of DOE-STD-1121-98 and should:

- provide for investigation of suspected intakes;
- provide data for evaluating internal dose; and
- provide results that are adequate to demonstrate compliance with the radiation dose limits given in 10 CFR 835. The primary methods of routine and special worker radiobioassay are direct (in vivo) radiobioassay and indirect (in vitro) radiobioassay.

International Commission on Radiological Protection (ICRP) Publication 54, *Individual Monitoring for Intakes of Radionuclides by Workers: Design and Interpretation* (ICRP 1989) as well as the previously referenced NCRP Report No. 87 are suggested supplementary references for individual monitoring program design. In situations where there is no practical radiobioassay, representative air monitoring (e.g. breathing zone (BZ) air monitoring) is the preferred measurement method on which to base dose evaluations. Additional guidance on air monitoring programs may be found in DOE G 441.1-8.

4.3.1 Establishing the Need for Individual Monitoring

Radiological workers who could likely receive intakes resulting in 0.1 rem or more committed effective dose equivalent in a year shall participate in an internal dose evaluation program (10CFR 835.402(c)(1)). Declared pregnant workers, occupationally exposed minors, and members of the public are also required, under specific conditions (see 10 CFR 835.402(c)) to participate in internal dosimetry programs. Criteria for participation in individual monitoring programs which include baseline radiobioassay, routine radiobioassay and/or air sampling, Radon and thoron monitoring, special radiobioassay, and termination or task-ending radiobioassay, radiobioassay for declared pregnant women, and confirmatory radiobioassay are covered in DOE-STD-1121-98, Section 5, Individual Monitoring for Internal Dosimetry. This section of the technical standard also discusses timely receipt of radiobioassay results. Participation in individual monitoring programs for internal dosimetry should be in accordance with the DOE technical standard. ICRP Publication 54 is also a recommended reference.

Situations may arise where a decision is made to monitor radiological workers who are not likely to receive intakes that exceed 0.1 rem committed effective dose equivalent in a year. Such monitoring may be useful for demonstrating compliance with 10 CFR 835.401(a) or established for other purposes. The internal dosimetry program documentation should clearly identify those individuals or groups of individuals being monitored for such purposes.

4.3.2 Investigation Levels/Derived Investigation Levels

Refer to DOE-STD-1121-98, Sections 4.3 and 4.4 for a discussion of and reference levels for Investigation Levels (*ILs*) and Derived Investigation Levels (*DILs*). Programs should be designed in accordance with this technical standard.

Refer to DOE-STD-1121-98, Section 4.4.1 for a discussion of factors affecting the *DIL*. Additionally, section 4.4.2 provides guidance for calculating the *DIL* for a given sample frequency, Section 4.4.3 discusses factors affecting the *DIL* for air sampling, and Section 4.4.4 deals with supplementing routine radiobioassay programs when *DIL*< *MDA* (technology shortfall). Programs should be designed in accordance with this technical standard.

4.3.3 Minimum Detectable Amount (MDA)

The internal dosimetry program staff should determine the minimum detectable amount (*MDA*) for each radiobioassay and BZ air monitoring method for each radionuclide present. The *MDA*s should be documented in procedures and their statistical bases given in the internal dosimetry technical basis documentation. ANSI Standard N13.30-1996, *Performance Criteria for Radiobioassay*, (ANSI 1996) provides extensive guidance on the calculation of *MDAs.*

As *MDAs* are affected by various aspects involved with individual monitoring methods, procedures should contain descriptions of the method(s) of individual monitoring measurements (e.g., urinalysis, fecal analysis, *in vivo* counting, BZ air monitoring), analytical methodology (e.g., chemical separation followed by alpha counting), and measurement parameters (e.g., counting time or instrument efficiency) to be used in each component of the individual monitoring program.

Several other factors affect the method of radiobioassay used and its associated *MDA*. They include:

- the possible need for improved detection capability to assess individual dose during the special radiobioassay following an intake requiring internal dose evaluation, due to diminishing amounts of material in compartments as time goes on;
- the need for improved precision and accuracy if residual retention and excretion from prior intakes interferes with the detection of additional intakes in subsequent years;
- timeliness of results needed to manage individuals and keep subsequent intakes low enough to avoid exceeding dose limits;
- convenience to the affected individuals;
- costs, including lost production time while individuals are participating in the radiobioassay program; and
- the impact of the method of radiobioassay on the frequency of radiobioassay measurements.

Where practicable, the method of individual monitoring, analytical methodology, and measurement parameters should result in an *MDA* less than the corresponding *DIL* for all radionuclides to which an individual might be exposed.

The methods of radiobioassay and air monitoring measurements, their *MDA*s, and their accuracies should be specified in the internal dosimetry technical basis documentation, along with a rationale or justification for the methods chosen.

4.3.4 Frequency of Measurement

The routine radiobioassay measurement frequency depends on the radiobioassay measurement method and associated *MDA*. The frequency should be chosen so that it is unlikely that intakes by an individual in a year will result in doses exceeding one *IL* without detection.

4.3.5 Detection and Confirmation of Intakes

Section 6 of DOE-STD-1121-98 provides acceptable methods for detecting and confirming intakes through workplace monitoring and radiobioassay. Statistical methods for confirming that an intake has occurred is also discussed. Decisions regarding the detection and confirmation of suspected occupational intakes of radioactive material should be based on answers to the following questions:

- Can it be concluded reliably that the analyte is present in the measured sample ($>L_c$)?

- Is the measurement result unexpected? In other words, is the result beyond the range of values that would be expected due to environmental "background" sources or due to previously recognized intakes?

- Is the intake (and resulting dose) implied by the measurement significant enough (e.g., greater than the *IL*) to warrant follow-up measurements or investigation?

If the answer to all these questions is "yes", then follow-up measurements or investigation is warranted. Internal dosimetry programs should establish appropriate and technically-based decision criteria to assist in answering these questions. Such decision criteria should be included in the technical basis document for the site or facility.

The proper decision criteria for the first question is the L_c which is a purely statistical concept based on an acceptable probability of "false positive" conclusions. The L_c for radiobioassay and air sample measurements should be set by considering the acceptable rate of false positives, the cost and consequences of false positives, and the dosimetric consequences of false negatives. The analytical laboratory L_c should be based on a reagent blank.

Radiobioassay results above the L_c may be expected in the absence of a new intake due to normal statistical fluctuations, non-occupational or environmental sources, or prior confirmed intakes. In the case of environmental sources of interference (e.g., uranium in urine) an "occupational decision level" should be established, above which the measurement result is concluded to be statistically significant and above the range of values that would normally be expected from environmental sources of the radionuclide. In the case of prior confirmed intakes, an individual-specific "occupational decision level" should be established, which takes into account the expected contribution from the prior intakes.

Finally, for each route of intake, measurement type, and radioactive material of interest (taking into account particle size, inhalation class, etc.), time-dependent *DILs* should be established. Such *DILs* are based solely on dosimetric considerations, and typically correspond to an implied intake (and corresponding dose) of 1 investigation level, i.e., 0.1 rem. This Guide has adopted the value of 0.1 rem CEDE as the value which, for

regulatory purposes, is regarded as sufficiently important to justify further investigation. However, a site or facility may wish to establish lower follow-up levels for ALARA purposes.

If the measurement result is statistically significant, unexpected, and dosimetrically significant, then follow-up measurements and/or an investigation should be done to attempt to confirm or rule out the intake. An intake should be considered to be confirmed if the three criteria above are satisfied and the measurement result is associated with a known incident, or appropriate follow-up measurements meet the three criteria above, or follow-up investigation indicates that an intake has occurred.

Refer to DOE-STD-1121-98, Section 6, for additional information on the detection and confirmation of intakes. Table 3 addresses reference levels for interpreting or responding to intake monitoring results. Program elements which address the detection and confirmation of intakes of radionuclides should be in accordance with the DOE technical standard. ANSI N13.30-1996 and ICRP Publication 54 are suggested references. Additionally, NCRP Report No. 84, *General Concepts for the Dosimetry of Internally Deposited Radionuclides* (NCRP 1985) and ICRP Publication 30, *Limits for Intakes of Radionuclides by Workers* (ICRP 1979), may be useful references.

4.3.6 Internal Dose Management

Internal dose management, which includes routine radiological worker dose management, management of dose from previous intakes (work restrictions), control of dose to the embryo/fetus, control of dose to minors and students, dose limitation, interface with the external dosimetry program, lifetime dose control, accidental dose control, and internal dose control after an incident, is covered in DOE-STD-1121-98, Section 8, Internal Dose Management. Individual programs should be in accordance with the DOE technical standard.

4.3.7 Planned Special Exposures

Planned special exposures are included in an individual's occupational dose record, but shall not be considered when determining compliance with the occupational dose limits of 10 CFR 835 (10CFR 835.204(a), (e)). In order to maintain separate records of doses resulting from planned special exposures and routine occupational exposures, dosimetry adequate to measure the potential doses and appropriate for the work to be performed and specific radiological circumstances should be provided for the planned special exposure.

4.3.8 Medical Response

Medical response is addressed in DOE-STD-1121-98, Section 10, Medical Response. The standard addresses situations where internal dosimetry actions and medical treatment occur simultaneously, the role of the health physicist in medical treatment, when to treat, how to treat, the impact of therapy on dosimetry, and the counseling of workers. Medical response should be handled in accordance with the DOE technical standard.

4.4 INTERNAL DOSE EVALUATION

10 CFR 835 requires internal dose evaluation programs for assessing intakes of radionuclides and for maintaining adequate worker exposure records. Technical details and extensive references for internal dose evaluation are given in DOE-STD-1121-98. ICRP Publications 30 and 54, NCRP Report No. 84, and ANSI N13.30 are additional suggested references.

4.4.1 Required Dose Calculations

Internal doses should be evaluated for all confirmed intakes, as defined in Section 4.3.5 of this guide. For intakes confirmed with radiobioassay results below the *DIL*, no further investigation or follow-up radiobioassay are indicated. For intakes confirmed with radiobioassay results above the *DIL* or exposures greater than 40 DAC-hours, follow-up radiobioassay (if practical) and investigation should be performed.

The extent of the investigation and the number and frequency of special radiobioassay measurements following a suspected or confirmed intake should be determined and documented on an individual, case-specific basis, taking into account the potential magnitude of the intake, the effective clearance half-time, the health of the worker, and the number of measurements needed to evaluate the internal dose.

The schedule and frequency of long-term special radiobioassay measurements to evaluate the CEDE to an individual who has had an intake resulting in a dose in excess of one *IL* should depend on the expected magnitude of the CEDE and the likelihood of the individual receiving additional intakes.

While the investigation should be tailored to the specific individual and exposure circumstances, the trigger levels and preliminary actions to be taken for exposures to the different radionuclides encountered at the facility should be documented in the internal dosimetry technical basis documentation and procedures.

4.4.2 Interpretation of Radiobioassay Data

Technical details on the interpretation of radiobioassay data including the use of biokinetic models are given in DOE-STD-1121-98, Section 7, Internal Dose Evaluation. Radiobioassay data should be interpreted in accordance with the applicable portions of this DOE technical standard.

Evaluations of CEDE from a specific intake should account for expected values of radiobioassay measurements from prior confirmed intakes.

4.4.3 Evaluation of Internal Dose from Radiobioassay and Air Monitoring Data

Methods for evaluating the various doses from intakes should be specified in the internal dosimetry technical basis documentation. The methods should be based on recommendations given in ICRP Publications, NCRP Reports, and ANSI standards which embody improvements and updates of the science of internal dosimetry. Other methods may be used provided they are documented and justified in the procedures and/or internal dosimetry technical basis documentation.

In the calculation of internal doses less than one *IL*, default parameters may be used. These parameters (e.g., intake date, deposition fractions , retention functions, organ masses, absorption fractions) should be based on the recommendations of the ICRP, NCRP, other relevant technical references, or facility-specific factors as documented in the internal dosimetry technical basis documentation.

If the initial evaluation of an intake indicates a dose in excess of 10 times an *IL*, individual-specific and facility-specific factors should be used when more appropriate parameters are expected to change the dose calculations by a factor of 1.5 or more (ICRP Publication 54, paragraph 74). Between 1 and 10 times the *IL*, either default parameters or individual- and facility-specific parameters may be used, as deemed appropriate and documented by the internal dosimetry staff. The basis for determining which individual-specific and facility-specific factors are

expected to change the dose calculations by a factor of 1.5 or more should be documented in the internal dosimetry technical basis documentation. Determination of individual retention patterns for a worker requires participation in the special radiobioassay program and may require temporary work restriction or reassignment to prevent subsequent intakes from confounding the dose evaluation.

4.4.4 Periodic Reevaluation of Internal Dose

In the case of certain well-retained radionuclides (e.g., plutonium), long-term follow-up and reevaluation of doses may be required. The internal contribution to lifetime occupational dose should continue to be reevaluated as further radiobioassay results and improved methods for evaluating internal dose become available.

Evaluations for general employees with prior confirmed intakes should be revised when information demonstrates a change in the currently evaluated CEDE of 0.5 rem (0.005 Sv) or a factor of 1.5 of the previously assigned dose for that intake, whichever is higher. In cases where intakes are detected or confirmed in a year subsequent to the year of the intake, the CEDE should be attributed to the known or assumed year of the intake, and all records and reports for that year should be amended as appropriate.

4.5 RECORDKEEPING AND REPORTING

Requirements and guidance for recording and reporting internal doses and related information are provided in 10 CFR 835 DOE G 441.1-11, OCCUPATIONAL RADIATION PROTECTION RECORD-KEEPING AND REPORTING GUIDE (DOE 1999d) and DOE-STD-1121-98, Section 9, Records and Reports. Record-keeping and reporting of internal doses and related information should be in accordance with these DOE documents.

5. REFERENCES

AEC (Atomic Energy Commission) 1954. U.S. Atomic Energy Act of 1954, as amended. Public Law 83-703 (68 Stat. 919), Title 42 U.S.C. sec. 2011.

ANSI (American National Standards Institute) 1996. ANSI/HPS N13.30-1996, *Performance Criteria for Radiobioassay*. McLean, VA 22101.

DOE (U.S. Department of Energy) 1997a. 10 CFR 820, U.S. Department of Energy, Procedural Rules for DOE Nuclear Activities. 58 FR 43680, *Federal Register* Vol. 58, No. 157, dated 10-8-97. Washington, D.C.

DOE 1997b. DOE-STD-1107-97. KNOWLEDGE, SKILLS, AND ABILITIES FOR KEY RADIATION PROTECTION POSITIONS AT DOE FACILITIES, dated 1-97. Washington, D.C.

DOE 1998a. 10 CFR 835, U.S. Department of Energy, Occupational Radiation Protection. 63 FR 59662, *Federal Register*, Vol. 63, No. 213, dated 11-4-98. Washington, D.C.

DOE 1998b. DOE-STD-1121-98. INTERNAL DOSIMETRY, under development at time of publication. Washington, D.C.

DOE 1998c. DOE-STD-1112-98. DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM FOR BIOASSAY, under development at time of publication. Washington, D.C.

DOE 1998d. DOE-STD-1111-98. DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM ADMINISTRATION, under development at time of publication. Washington, D.C.

DOE 1999a. DOE G 441.1-1. MANAGEMENT AND ADMINISTRATION OF RADIATION PROTECTION PROGRAMS GUIDE, dated 3-17-99. Washington, D.C.

DOE 1999b. DOE G 441.1-9. RADIOACTIVE CONTAMINATION CONTROL GUIDE, under development at time of publication. Washington, D.C.

DOE 1999c. DOE G 441.1-8. AIR MONITORING GUIDE, dated 3-17-99. Washington, D.C.

DOE 1999d. DOE G 441.1-11 OCCUPATIONAL RADIATION PROTECTION RECORD-KEEPING AND REPORTING GUIDE, under development at time of publication. Washington, D.C.

ICRP (International Commission on Radiological Protection) 1979. ICRP Publication 30. *Limits for Intakes of Radionuclides by Workers: Design and Interpretation*., dated 1979 Pergamon Press. New York, New York.

ICRP 1989. ICRP Publication 54, *Individual Monitoring for Intakes of Radionuclides by Workers: Design and Interpretation*, dated 1989. Pergamon Press. New York, New York.

NCRP (National Council on Radiation Protection and Measurements) 1985. NCRP Report No. 84.,*General Concepts for the Dosimetry of Internally Deposited Radionuclides*, dated 1985. Bethesda, Maryland.

NCRP 1987. NCRP Report No. 87, *Use of Radiobioassay Procedures for Assessment of Internal Radionuclide Deposition*, dated 1987. Bethesda, Maryland.

6. SUPPORTING DOCUMENTS

American National Standards Institute. *Internal Dosimetry Programs for Tritium Exposure--Minimum Requirements*. ANSI N13.14-1983. New York, New York. 1983.

Faust, L. G., *et al*. Health Physics Manual of Good Practices for Plutonium Facilities. PNL-6534. Pacific Northwest Laboratory. Richland, Washington. 1988.

International Commission on Radiological Protection. *Report of the Task Group on Reference Man*. ICRP Publication 23. Pergamon Press. New York, New York. 1975.

International Commission on Radiological Protection. *The Metabolism of Plutonium and Related Elements*. ICRP Publication 48. Pergamon Press. New York, New York. 1986.

Johnson, J. R. and M. B. Carver. A General Model for Use in Internal Dosimetry. *Health Physics*, 40:341-348. 1981

Johnson, J. R. and R. C. Myers.. Alkaline Earth Metabolism: A Model Useful in Calculating Organ Burdens, Excretion Rates, and Committed Effective Dose Equivalent Conversion Factors. *Radiation Protection Dosimetry*, 1(2):87-95. 1981.

Lawrence, J. N. P. A History of PUQFUA - Plutonium Body Burden (Q) From Urine Assays. LA-7403-H. Los Alamos National Laboratory. Los Alamos, New Mexico. 1978.

Leggett, R. W. and K. F. Eckerman.. Estimating Systemic Pu Burden From Urinalyses. *Health Physics*, 52:337-346. 1987.

Lessard, E. T., *et al.* Interpretation of Radiobioassay Measurements. NUREG/CR-4884. Brookhaven National Laboratory. Upton, New York. 1987.

Rich, B. L., *et al*. Health Physics Manual of Good Practices for Uranium Facilities. EGG-2530. EG&G Idaho, Inc. Idaho Falls, Idaho. 1988.

Sikov, M. R., *et al*. Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses. NUREG/CR-5631, Rev. 1. U.S. Nuclear Regulatory Commission. Bethesda, MD. 1992.

U.S. Department of Energy. RADIOLOGICAL CONTROL. DOE-STD-1098-99. Under development at time of publication. Washington, D.C. 1999.

U.S. Environmental Protection Agency. *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion*. Federal Guidance Report No. 11, EPA-520/1-88-020. Washington, D.C. 1988.

Watson, S. B. and M. R. Ford. A User's Manual to the ICRP Code–A Series of Computer Programs to Perform Dosimetric Calculations for the ICRP Committee 2 Report. ORNL/TM-6980. Oak Ridge National Laboratory. Oak Ridge, Tennessee. 1980.

UNITED STATES
DEPARTMENT OF ENERGY

Office of Worker Protection Programs and Hazards Management (EH-52/270CC)
19901 Germantown Road, Germantown, MD 20874-1290

Request for Changes to

INTERNAL DOSIMETRY PROGRAM GUIDE

(Use multiple pages as necessary.)

Page No. _____	Facility Requesting Change:_____
Column No. _____	Contact Person:_____
Line No. _____	Telephone No./Fax No.:_____

Description of Change Request:

_____

_____

_____

_____

Suggested Specific Word Changes:

_____

_____

_____

_____

EH-52 Technical Staff Contact
Bob Loesch
(301) 903-4443

EH-52 Technical Staff Contact
Joel L. Rabovsky
301-903-2135